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DOCKET NO.: I0248.70024US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Adams et al.
Serial No.: 10/616,409
Confirmation No.: 9289
Filed: July 9, 2003
For: BOROPROLINE COMPOUND COMBINATION THERAPY
Examiner: Not Yet Assigned
Art Unit: 1645

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 28th day of April, 2005.


Kristin J. Ketelhut

MAIL STOP AMENDMENT

Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

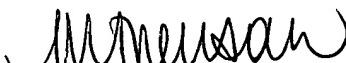
- Information Disclosure Statement
- PTO Form 1449 with cited references
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,
Adams et al., Applicant

By:



Maria A. Trevisan, Reg. No.: 48,207
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
Telephone: (617) 646-8000

Docket No.: I0248.70024US00

Date: April 28, 2005

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing date of a first Office Action on the merits in the above-identified case.

No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The above-identified U.S. application claims priority to application Serial No. PCT/US2003/021547. If the Examiner has not had the benefit of review of the file history of PCT/US2003/021547, then he/she is asked to contact the undersigned, who will provide a copy of same.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

| <u>Docket No.</u> | <u>Serial No.</u> | <u>Filing Date</u> | <u>Inventor(s)</u> |
|-------------------|-------------------|--------------------|--------------------|
| I0248.70012US00 | 09/578,363 | 25 May 2000 | Wallner et al. |
| I0248.70013US00 | 09/290,376 | 12 April 1999 | Wallner |
| I0248.70014US00 | 09/744,658 | 13 August 1999 | Wallner |
| I0248.70022WO00 | PCT/US2005/00079 | 10 January 2005 | McLean et al. |
| *I0254.70007US01 | 11/030,591 | 6 January 2005 | Bachovchin |
| *I0254.70008US01 | 10/775,598 | 10 February 2004 | Bachovchin |
| *I0254.70014US01 | 10/778,667 | 13 February 2004 | Huber |

*a copy of this reference is not provided as the Office hereby waives the requirement under 37 CFR 1.98(a)(2)(iii) for submitting a copy of each cited U.S. patent application filed after June 30, 2003 and for applications filed before June 30, 2003, or that entered the national stage before June 30, 2003, if they are scanned to Image File Wrapper system and are available on Private PAIR.

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,
Adams et al., Applicant

By:



Maria A. Trevisan, Reg. No. 48,207
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
Telephone: (617) 646-8000

Docket No.: I0248.70024US00

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

| | | | |
|-------------------------|--|-----------------------------|-----------------------------------|
| Sheet 1 of 4 | | | |
| | | APPLICATION NO.: 10/616,409 | ATTY. DOCKET NO.: 10248.70024US00 |
| | | FILING DATE: July 9, 2003 | CONFIRMATION NO.: 9289 |
| APPLICANT: Adams et al. | | | |
| | | GROUP ART UNIT: 1645 | EXAMINER: Not Yet Assigned |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|----------|----------------------|-----------|---|--|
| Examiner's Initials | Cite No. | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication or of issue of Cited Document MM-DD-YYYY |
| | | Number | Kind Code | | |
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| | A31 | 2005-0037976 | A1 | Wallner et al. | 02-17-2005 |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|----------|-------------------------|-----------|---|--|------------|
| Examiner's Initials | Cite No. | Foreign Patent Document | | Name of Patentee or Applicant of Cited Document (not necessary) | Date of Publication of Cited Document MM-DD-YYYY | |
| | | Office/Country | Number | Kind Code | | |
| | B1 | EP | 0 371 467 | A2 | Hoechst Aktiengesellschaft | 06-06-1990 |
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| FORM PTO-1449/A and B (Modified) INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | APPLICATION NO.: 10/616,409 | ATTY. DOCKET NO.: I0248.70024US00 | | |
| | | | | FILING DATE: July 9, 2003 | CONFIRMATION NO.: 9289 | | |
| | | | | APPLICANT: Adams et al. | | | |
| | | | | GROUP ART UNIT: 1645 | EXAMINER: Not Yet Assigned | | |
| Sheet | 2 | of | 4 | | | | |

| Examiner's Initials | Cite No. | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Document (not necessary) | Date of Publication of Cited Document MM-DD-YYYY | Translation (Y/N) |
|---------------------|----------|-------------------------|-------------|-----------|--|---|-------------------|
| | | Office/ Country | Number | Kind Code | | | |
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| | B5 | WO | 91/16339 | A1 | New England Medical Center Hospitals, Inc. | 10-31-1991 | |
| | B6 | WO | 91/17767 | A1 | New England Medical Center Hospitals, Inc. | 11-28-1991 | |
| | B7 | WO | 92/12140 | A1 | Georgia Tech Research Corporation | 07-23-1992 | |
| | B8 | WO | 93/08259 | A2 | New England Medical Center Hospitals, Inc. | 04-29-1993 | |
| | B9 | WO | 93/10127 | A1 | Boehringer Ingelheim Pharmaceuticals, Inc. | 05-27-1993 | |
| | B10 | WO | 93/16102 | A1 | Dana-Farber Cancer Institute | 08-19-1993 | |
| | B11 | WO | 94/03055 | A1 | The Government of the United States of America | 02-17-1994 | |
| | B12 | WO | 94/09132 | A1 | Dana-Farber Cancer Institute | 04-28-1994 | |
| | B13 | WO | 95/11689 | A1 | Trustees of Tufts College | 05-04-1995 | |
| | B14 | WO | 95/15309 | A1 | Ferring B.V. | 06-08-1995 | |
| | B15 | WO | 98/00439 | A2 | Trustees of Tufts College | 01-08-1998 | |
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| | B21 | WO | 00/10549 | A1 | Point Therapeutics, Inc. | 03-02-2000 | |
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| | | WO | 2004/004661 | A2 | Point Therapeutics, Inc. | 01-15-2004 | |

OTHER ART – NON PATENT LITERATURE DOCUMENTS

| Examiner's Initials | Cite No | Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published. | Translation (Y/N) |
|---------------------|---------|---|-------------------|
| | C1 | BAKER et al., Hydroxamates and aliphatic boronic acids: marker inhibitors for aminopeptidase. Biochemistry. 1983 Apr 26;22(9):2098-103. | |
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| | C4 | JIANG et al., Inhibition of human immunodeficiency virus type 1 infection in a T-cell line (CEM) by new dipeptidyl-peptidase IV (CD26) inhibitors. Res Virol. 1997 Jul-Aug;148(4):255-66. | |
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|---------------------|---------|--|-------------------|
| | C7 | KETTNER et al., Kinetic properties of the binding of alpha-lytic protease to peptide boronic acids. Biochemistry. 1988 Oct 4;27(20):7682-8. | |
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| | C10 | KINDER et al., Analogues of carbamyl aspartate as inhibitors of dihydroorotate: preparation of boronic acid transition-state analogues and a zinc chelator carbamylhomocysteine. J Med Chem. 1990 Feb;33(2):819-23. | |
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| | C12 | KUBOTA et al., Involvement of dipeptidyl peptidase IV in an in vivo immune response. Clin Exp Immunol. 1992 Aug;89(2):192-7. | |
| | C13 | KUBOTA et al., Dipeptidyl peptidase IV (DP IV) activity in serum and on lymphocytes of MRL/Mp-lpr/lpr mice correlates with disease onset. Clin Exp Immunol. 1994 May;96(2):292-6. | |
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| | C21 | SNOW et al., Studies on Proline Boronic Acid Dipeptide Inhibitors of Dipeptidyl Peptidase IV: Identification of a Cyclic Species Containing a B-N Bond. J Am Chem Soc. 1994;116:10860-9. | |
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| | C23 | TANAKA et al., Cloning and functional expression of the T cell activation antigen CD26. J Immunol. 1992 Jul 15;149(2):481-6. Erratum in: J Immunol. 1993 Mar 1;150(5):2090. | |
| | C24 | TANAKA et al., The costimulatory activity of the CD26 antigen requires dipeptidyl peptidase IV enzymatic activity. Proc Natl Acad Sci U S A. 1993 May 15;90(10):4586-90. Abstract Only. | |
| | C25 | THOMPSON et al., Chapter 19: Peptide aldehydes: potent inhibitors of serine and cysteine proteases. in Methods in Enzymology, Volume 46. Colowick et al., eds. p220-5. | |

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| | | | | APPLICANT: Adams et al. | | | |
| | | | | Sheet | 4 | of | 4 |

| Examiner's Initials | Cite No | Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published. | Translation (Y/N) |
|---------------------|---------|---|-------------------|
| | C26 | WELCH et al., Fluoroolefin containing dipeptide isosteres as inhibitors of dipeptidyl peptidase IV(CD26). Tetrahedron. 1996 January 1;52(1):291-304. | |
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|-----------|------------------|
| EXAMINER: | DATE CONSIDERED: |
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. ___, filed ___, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE - The Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC 371 after June 30, 2003. See 37 CFR 1.491(b). For all patent applications filed on or before June 30, 2003, copies of cited U.S. patents and patent application publications are still required unless an eIDS is filed. Copies of all other patent(s), publication(s), or other information listed must still be provided, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]